



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,790	02/11/2004	Jacqueline C. Timans	DX01040K3B	3044

28008 7590 10/03/2006

DNAX RESEARCH INC.  
LEGAL DEPARTMENT  
901 CALIFORNIA AVENUE  
PALO ALTO, CA 94304

EXAMINER

JIANG, DONG

ART UNIT	PAPER NUMBER
----------	--------------

1646

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/777,790	Applicant(s) TIMANS ET AL.	
	Examiner Dong Jiang	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

### DETAILED ACTION

Currently, claims 1-25 are pending.

#### Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-7, drawn to a polynucleotide, a vector containing same, a host cell thereof, and a method of recombinantly producing the encoded polypeptide, classified in class 435, subclass 69.5.
  - II. Claims 8-10, drawn to a method of hybridization, and a kit containing a polynucleotide fragment (probe) for hybridization, classified in class 435, subclass 6.
  - III. Claims 11, 12, and 15, drawn to a binding composition, and a kit containing same, classified in class 530, subclass 387.9.
  - IV. Claims 13 and 14, drawn to a method of detecting an antigen with said antibody, classified in class 436, subclass 501.
  - V. Claims 16-18, drawn to a polypeptide, classified in class 530, subclass 351.
  - VI. Claims 19 in part, and 20 in part, drawn to a method of modulating a cell activity with an agonist of IL-D80, or in combination with an IL-12 agonist, classification depending upon the chemical entity of the agonists.
  - VII. Claims 19 in part, and 20 in part, drawn to a method of modulating a cell activity with an agonist of IL-D80, or in combination with an IL-12 antagonist, classification depending upon the chemical entity of the agonists.
  - VIII. Claims 19 in part, and 20 in part, drawn to a method of modulating a cell activity with an antagonist of IL-D80, or in combination with an IL-12 agonist, classification depending upon the chemical entity of the agonists.
  - IX. Claims 19 in part, and 20 in part, drawn to a method of modulating a cell activity with an antagonist of IL-D80, or in combination with an IL-12 antagonist, classification depending upon the chemical entity of the agonists.

Art Unit: 1646

- X. Claims 19 in part, and 20 in part, drawn to a method of modulating a cell activity with an agonist of IL-27, or in combination with an IL-12 agonist, classification depending upon the chemical entity of the agonists.
- XI. Claims 19 in part, and 20 in part, drawn to a method of modulating a cell activity with an agonist of IL-27, or in combination with an IL-12 antagonist, classification depending upon the chemical entity of the agonists.
- XII. Claims 19 in part, and 20 in part, drawn to a method of modulating a cell activity with an antagonist of IL-27, or in combination with an IL-12 agonist, classification depending upon the chemical entity of the agonists.
- XIII. Claims 19 in part, and 20 in part, drawn to a method of modulating a cell activity with an antagonist of IL-27, or in combination with an IL-12 antagonist, classification depending upon the chemical entity of the agonists.
- XIV. Claim 21, drawn to a composite comprising a plurality of segments of said polypeptides, classified in class 514, subclass 2.
- XV. Claim 22, drawn to an isolated polynucleotide encoding the composite, classified in class 536, subclass 23.5.
- XVI. Claim 23, drawn to a binding composition binding to an antigenic fragment of composite comprising a plurality of segments of said polypeptides, classified in class 530, subclass 387.1.
- XVII. Claim 24, drawn to a receptor subunit:ligand composition, classified in class 514, subclass 2.
- XVIII. Claim 25, drawn to a binding composition binding to the receptor subunit:ligand composition, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because:

The polynucleotide of Invention I can be related to the method of Invention II as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide of Invention I may be used for the production of the polypeptide of Invention V.

The products of Invention I are distinct and unrelated from the binding compositions (antibody) of Inventions III, XVI and XVIII, the composite of Invention XIV, and the receptor subunit:ligand composition of Invention XVII because they are physically and functionally distinct chemical entities which share neither structure nor function. The method of Invention I is distinct and unrelated from the products of Inventions III, XIV and XVI-XVIII because the products may be neither made by nor used in the method.

Invention I is distinct from and unrelated to Inventions IV and VI-XIII, wherein the products of Invention I can be neither made by nor used in the methods of Inventions IV and VI-XIII, and wherein each does not require the other.

The polynucleotide of Invention I is related to the polypeptide of Invention V by virtue of encoding same. The polynucleotide has utility for the recombinant production of the protein in a host cell. Although the polynucleotide and the protein are related since the polynucleotide encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the polynucleotide may be used for processes other than the production of the protein, such as nucleic acid hybridization assay of Invention II.

The method of Invention I are related to the polypeptide of Inventions V as process of making and product made. The Inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP 806.05(f)). In the instant case the product as claimed may be isolated from their natural source or made by chemical peptide synthesis.

Although both Inventions I and XV are directed to polynucleotides, they are distinct because Invention XV comprises additional and multiple polynucleotides, thus separate searches are required for the inventions.

Invention II is distinct from and unrelated to Inventions III, V and XIV-XVIII, wherein the products of Inventions III, V and XIV-XVIII can be neither made by nor used in the method of Invention II, and wherein each does not require the other. Further, the polynucleotide probe

Art Unit: 1646

of Invention II is distinct from the products of Inventions III, V and XIV-XVIII because they are physically and functionally distinct chemical entities which share neither structure nor function.

Invention II is distinct from and unrelated to Inventions IV and VI-XIII, wherein the polynucleotide probe of Invention II can be neither made by nor used in the methods of Inventions IV and VI-XIII, and wherein each does not require the other. Further, the method of invention II is distinct from and unrelated to the methods of Inventions IV and VI-XIII, as it is drawn to a method having different process steps, different active agents, different starting and ending points from the methods of Inventions IV and VI-XIII, and is for a different purpose, such that they require separate searches.

Invention III is related to Invention IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody of Invention III may be used for the purification of the polypeptide of Invention V.

The polypeptide of Invention V is related to the antibody of Invention III by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or in assays for the identification of agonists or antagonists of the receptor protein.

Invention III is distinct from and unrelated to Inventions VI-XIII, wherein the product of Invention III can be neither made by nor used in the methods of Inventions VI-XIII, and wherein each does not require the other.

The antibody composition of Invention III is distinct from the products of Inventions XIV, XV and XVII because they are physically and functionally distinct chemical entities which share neither structure nor function.

Although Inventions III, XVI and XVIII are directed to a binding composition, they are distinct because they are specific for binding partners having distinct structures, thus separate searches are required for the inventions.

Invention IV is distinct from and unrelated to Inventions V and XIV-XVIII, wherein the products of Inventions V and XIV-XVIII can be neither made by nor used in the method of Invention IV, and wherein each does not require the other.

Inventions IV, and VI-XIII are drawn to independent methods, wherein each of the methods has different process steps, different active agents, different starting and ending points, and is for a different purpose, such that they require separate searches.

Invention V is distinct from and unrelated to Inventions VI-XIII, wherein the product of Invention V can be neither made by nor used in the method of Inventions VI-XIII, and wherein each does not require the other.

Although both Inventions V and XIV are directed to polypeptides, they are distinct because Invention XIV comprises additional and multiple polypeptides, thus separate searches are required for the inventions.

The polypeptide of Invention V is distinct from the products of Inventions XV-XVIII because they are physically and functionally distinct chemical entities which share neither structure nor function.

Inventions VI-XIII are drawn to independent methods, wherein each of the methods has different active element such as an agonist vs. an antagonist, or IL-27 vs. IL-D80, and is for a different purpose, as such they require separate searches.

Inventions VI-XIII are distinct from and unrelated to Inventions XIV-XVIII, wherein the products of Inventions XIV-XVIII can be neither made by nor used in the methods of Inventions VI-XIII, and wherein each does not require the other.

The composite of Invention XIV is related to the polynucleotide of Invention XV by virtue of encoded thereby. The polynucleotide has utility for the recombinant production of the protein in a host cell. Although the polynucleotide and the protein are related since the polynucleotide encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification

from the natural source. Further, the polynucleotide may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The polypeptides of Invention XIV are related to the antibody of Invention XVI by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary steric complementarity of the two, they are distinct inventions because they are physically and functionally distinct chemical entities, and because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right.

The polypeptide of Invention XIV is distinct from the products of Inventions XVII and XVIII because they are physically and functionally distinct chemical entities which share neither structure nor function.

The binding compositions of Inventions XVI and XVIII are distinct from the receptor subunit:ligand composition of Invention XVII because they are physically and functionally distinct chemical entities which share neither structure nor function.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

2. Furthermore, if applicants elect any one of the groups set forth above, further **restriction** is required under 35 U.S.C. 121:

- A. If one group is elected from Groups I-XIII, applicant is required to further elect one specific polypeptide with SEQ ID NO from the following: SEQ ID NO:2, 4, 6 or 8.
- B. If one group is elected from Groups XIV-XVIII, applicant is required to further specify which SEQ ID NOs (2, 4, 6, 8, 10 and 12) are included in the composite, or in the receptor subunit:ligand composition.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the



Art Unit: 1646

following reasons. Each of SEQ ID NOs, is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of the invention from Groups I-XVIII, and an election of the invention from Group A and/or B, to be examined even though the requirement be traversed (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention. Applicant is advised that neither I-XVIII nor A and B are species election requirements; rather, each of I-XVIII, A and B is a restriction requirement.**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim

Art Unit: 1646

will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

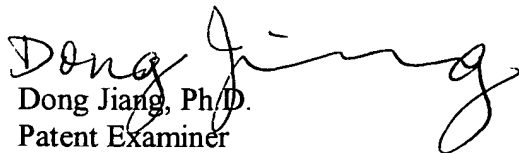
Art Unit: 1646

**Advisory Information**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dong Jiang, Ph.D.

Patent Examiner

AU1646

8/28/06